IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC., Plaintiffs, v. BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC., Defendants.	C.A. No. 05-00381 (KAJ) **JURY TRIAL DEMANDED**

BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO COMPLAINT

Defendants Barr Laboratories, Inc., and Barr Pharmaceuticals, Inc., ("Defendants"), by and through the undersigned attorneys, answer the Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. ("Plaintiffs"), as follows:

ANSWER

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1, and therefore deny the same.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2, and therefore deny the same.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore deny the same.

4. Defendants admit that Barr Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, New York, 10970. Defendants admit that Barr

Laboratories, Inc. is registered to do business and does business in the State of Delaware. Defendants deny the remaining allegations of paragraph 4.

5. Defendants admit that Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware. Defendants admit that Barr Pharmaceuticals, Inc. is registered to do business and does business in the State of Delaware. Defendants admit that Barr Pharmaceuticals, Inc. is the parent corporation of Barr Laboratories, Inc. and that Barr Laboratories, Inc. is a wholly-owned subsidiary of Barr Pharmaceuticals, Inc. Defendants deny the remaining allegations of paragraph 5.

6. Defendants deny the allegations of paragraph 6.

7. Paragraph 7 is a characterization of Plaintiffs' Complaint and contains conclusions of law rather than allegations of fact for which a response is required. Insofar as a response is required, Defendants admit that Plaintiffs allege that Defendants infringe U.S. Patent No. 4,663,318 ("the '318 patent") and seek relief under the patent laws of the United States of America. Defendants further admit, insofar as a response is required, that subject matter jurisdiction is proper in this Court.

8. Paragraph 8 contains conclusions of law rather than allegations of fact for which a response is required. Insofar as a response is required, Defendants admit that Barr Laboratories, Inc. is subject to personal jurisdiction in this judicial district. Defendants deny the remaining allegations of paragraph 8.

9. Paragraph 9 contains conclusions of law rather than allegations of fact for which a response is required. Insofar as a response is required, Defendants admit that Barr Pharmaceuticals, Inc. is subject to personal jurisdiction in this judicial district. Defendants deny the remaining allegations of paragraph 9.

10. Paragraph 10 contains conclusions of law rather than allegations of fact for which a response is required.

11. Paragraph 11 contains conclusions of law rather than allegations of fact for which a response is required. To the extent that a response is required, Defendants state that the rules governing the marketing of a "pioneering drug" are covered by 21 U.S.C. § 355 et al. and that the statute speaks for itself. Defendants deny the remaining allegations of paragraph 11.

12. Paragraph 12 contains conclusions of law rather than allegations of fact for which a response is required. To the extent that a response is required, Defendants state that the rules governing the marketing of a generic drug and the information that must be contained in an ANDA are covered by 21 U.S.C. § 355 et al. and that the statute speaks for itself. Defendants deny the remaining allegations of paragraph 12.

13. Paragraph 13 contains conclusions of law rather than allegations of fact for which a response is required. To the extent that a response is required, Defendants state that the rules governing the information that must be included in an ANDA are covered by 21 U.S.C. § 355 et al. and that the statute speaks for itself. Defendants deny the remaining allegations of paragraph 13.

14. Paragraph 14 contains conclusions of law rather than allegations of fact for which a response is required. To the extent that a response is required, Defendants state that the rules governing approval of conditions of use in ANDAs are covered by 21 U.S.C. § 355 et al. and that the statute speaks for itself. Defendants deny the remaining allegations of paragraph 14.

15. Paragraph 15 contains conclusions of law rather than allegations of fact for which a response is required. To the extent that a response is required, Defendants state that the rules governing the marketing of a "new drug" and the marketing of a "generic version of a drug" are

covered by 21 U.S.C. § 355 et al. and that the statute speaks for itself. Defendants deny the remaining allegations of paragraph 15.

16. Defendants admit that "Janssen is the holder of approved New Drug Application, NDA No. 21-169, for galantamine hydrobromide tablets." Defendants further admit that Janssen's "NDA was approved by FDA on February 28, 2001 and covers three strengths of tablet – Eq. 4 mg base, 8 mg base and 12 mg base." Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16, and therefore deny the same.

17. Defendants admit that Janssen currently markets a commercial formulation of galantamine hydrobromide tablets under the trademark RAZADYNE® for the indications approved of by the FDA. Defendants admit that Janssen also marketed a commercial formulation of galantamine hydrobromide tablets under the trademark REMINYL®. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17, and therefore deny the same.

18. Defendants admit that the '318 patent is listed in the FDA's Orange Book in connection with NDA No. 21-169. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18, and therefore deny the same.

19. Paragraph 19 contains conclusions of law rather than allegations of fact for which a response is required. To the extent that a response is required, Defendants state that the '318 patent is listed in the Orange Book in connection with NDA No. 21-169. Defendants further admit that Barr Laboratories, Inc. has not challenged the listing of the '318 patent in the Orange Book to date. Defendants deny the remaining allegations of paragraph 19.

20. Paragraph 20 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants admit that, under 21 U.S.C. 355(j), Barr Laboratories, Inc. filed with the FDA an Abbreviated New Drug Application ("ANDA"), which the FDA assigned No. 77-605, and Paragraph IV Certifications under section 505(j) of the FDCA, before May 13, 2005, to obtain approval to engage in the commercial manufacture, use or sale of galantamine hydrobromide tablets. In further answering, Defendants state that Barr Laboratories, Inc. disclosed to the FDA that its ANDA products were bioequivalent to Janssen's RAZADYNE® products. In further answering, Defendants state that Barr Laboratories, Inc. submitted a Paragraph IV Certification to ANDA No. 77-605 under 21 U.S.C. 355(j)(2)(A)(vii)(iv) of the Federal Food, Drug and Cosmetic Act to include a certification that the '318 patent was invalid, unenforceable and/or not infringed by Barr Laboratories, Inc.'s ANDA products. Defendants deny the remaining allegations of paragraph 20.

21. Defendants admit that the condition of use for which Barr Laboratories, Inc. seeks approval in its ANDA No. 77-605 for its galantamine hydrobromide tablets is for the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use approved in NDA No. 21-169. Defendants deny the remaining allegations of paragraph 21.

22. Defendants admit that the indication set forth in the proposed labeling submitted by Barr Laboratories, Inc. in its ANDA No. 77-605 for its galantamine hydrobromide tablets is for the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for the commercial formulation of galantamine hydrobromide tablets which is marketed under the trademarks RAZADYNE® and REMINYL®. Defendants deny the remaining allegations of paragraph 22.

23. Defendants reassert and reincorporate herein their answers to paragraphs 1-22.

24. Paragraph 24 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants admit that the '318 patent is entitled "Method of Treating Alzheimer's Disease," and that a copy of the '318 patent was attached as Exhibit A to the Complaint. Defendants admit that the face page of the '318 patent indicates that the '318 patent was issued on May 5, 1987. Defendants deny the remaining allegations of paragraph 24.

25. Paragraph 25 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants state that they are without knowledge as to the allegations in paragraph 25, and therefore deny the same.

26. Paragraph 26 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26, and therefore deny the same.

27. Paragraph 27 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27, and therefore deny the same.

28. Paragraph 28 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants deny the allegations of paragraph 28.

29. Paragraph 29 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants deny the allegations of paragraph 29.

30. Paragraph 30 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants deny the allegations of paragraph 30.

31. Paragraph 31 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants deny the allegations of paragraph 31.

32. Paragraph 32 contains conclusions of law for which no response is required. Insofar as a response is required, Barr Labs admits that it had knowledge of the '318 patent prior to filing its ANDA No. 77-605. Defendants deny the remaining allegations of paragraph 32.

33. Paragraph 33 contains conclusions of law for which no response is required. Insofar as a response is required, Defendants deny the allegations of paragraph 33.

AFFIRMATIVE DEFENSES

34. All of the claims of the '318 patent are invalid under one or more sections of 35 U.S.C. §§ 101, 102, 103, and 112.

35. One or more of Barr Laboratories, Inc.'s ANDA products do not infringe any valid and enforceable claims of the '318 patent.

36. Barr Pharmaceuticals, Inc. is not a proper party to this action.

37. Any additional defenses or counterclaims that discovery may reveal.

WHEREFORE, Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. pray that the Court enter judgment against Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. and in favor of Defendants, dismissing with prejudice each of the claims asserted by Plaintiffs, that the Court award Defendants their attorneys fees and costs, and that the Court award Defendants any other relief as it deems to be just and proper.

COUNTERCLAIMS

Defendant/Counterclaim Plaintiff Barr Laboratories, Inc., by and through its undersigned attorneys, hereby alleges, for its counterclaims against Plaintiffs/Counterclaim Defendants Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc., as follows:

Parties

38. Barr Laboratories, Inc. is a corporation having its corporate offices and a principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, NY 10970.

39. On information and belief, Janssen Pharmaceutica N.V. is a wholly-owned subsidiary of Johnson & Johnson, and is a corporation organized and existing under the laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

40. On information and belief, Janssen, L.P. is a wholly-owned subsidiary of Johnson & Johnson, and is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbouton Road, Titusville, New Jersey 08560.

41. On information and belief, Synaptech, Inc. is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwarts & Salomon, P.C., 225 Broadway, New York, New York 10007.

Jurisdiction and Venue

42. This action arises under the patent laws of the United States of America. Jurisdiction is founded on Title 28, United States Code 1331, 1338(a).

43. Venue is proper in this Court under Title 28, United States Code 1391(b), 1391(c) and 1400(b).

Background

44. Janssen is the holder of an approved New Drug Application ("NDA") No. 21-169 to market a commercial formulation of galantamine hydrobromide tablets, 4 mg base, 8 mg base, and 12 mg base. On information and belief, Janssen markets and sells its commercial product under the trade name RAZADYNE®.

45. The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") authorize a generic drug company to submit an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA"). The FDA will approve an ANDA if the generic company shows that its product has the same active ingredient as, and is "bioequivalent" to, a product that the FDA already has approved.

46. The FDCA requires NDA holders to disclose to the FDA the patent numbers and expiration dates of patents claiming the "drug" for which the NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2). The FDA then lists those patents in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly called the "Orange Book."

47. If a generic company seeks approval to market its generic product before a patent listed in the Orange Book expires, the generic company's ANDA must include a "certification" that the patent is invalid, unenforceable, or would not be infringed by the generic product. This type of certification is commonly called a "Paragraph IV Certification."

48. The ANDA applicant must send both the NDA holder and the patent holder a notice letter that includes a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is invalid, unenforceable, and/or would not be infringed. Moreover, pursuant to 21 U.S.C. § 355(j)(5)(C), the ANDA applicant must include within its

notice letter an "offer of confidential access" to its ANDA, which provides the NDA holder the opportunity to inspect the ANDA "for the purpose of determining whether" it should file suit against the ANDA holder.

49. The FDA "Orange Book" lists the '318 patent as a reference patent for Janssen's NDA No. 21-169.

50. Barr Laboratories, Inc. filed with the FDA an ANDA, which the agency assigned No. 77-605, with Paragraph IV Certifications to obtain approval to engage in the manufacture, use or sale of galantamine hydrobromide tablets ("Barr Laboratories, Inc.'s ANDA products").

51. On May 13, 2005, Barr Laboratories, Inc. sent to Plaintiffs a statutorily-required notice letter containing a detailed factual and legal statement as to why the '318 patent was invalid, unenforceable and/or not infringed by Barr Laboratories, Inc.'s ANDA products. Within its notice letter and pursuant to 21 U.S.C. § 355(j)(5)(C), Barr Laboratories, Inc. offered to provide its ANDA to Plaintiffs. Plaintiffs subsequently requested Barr Laboratories, Inc.'s ANDA No. 77-605 on May 25, 2005, and Barr Laboratories, Inc. provided such ANDA to Plaintiffs on June 3, 2005.

52. On June 10, 2005, Plaintiffs filed their patent infringement lawsuit against Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. Plaintiffs' complaint alleged that Barr Laboratories, Inc.'s ANDA products would infringe the '318 patent, which Barr Laboratories, Inc. has denied herein.

Counterclaim I
Declaration of Invalidity of the '318 Patent

53. Barr Laboratories, Inc. re-alleges and incorporates herein the allegations of paragraphs 38-52.

54. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that some or all of the claims of the '318 patent are invalid.

55. Jurisdiction over this counterclaim is proper under 28 U.S.C. §§ 1331, 1338(a), and 2201-2202. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

56. Plaintiffs/Counterclaim Defendants allege that the '318 patent is infringed, valid, and enforceable, and Barr Laboratories, Inc. denies those allegations.

57. There is an actual, substantial, continuing justiciable controversy between Barr Laboratories, Inc. and Plaintiffs/Counterclaim Defendants regarding the validity of the '318 patent.

58. Barr Laboratories, Inc. is entitled to a declaration that all of the claims of the '318 patent are invalid under one or more sections of 35 U.S.C. §§ 101, 102, 103 and/or 112.

59. Any additional defenses or counterclaims that discovery may reveal.

Counterclaim II
Declaration of Non-Infringement of the '318 Patent

60. Barr Laboratories, Inc. re-alleges and incorporates herein the allegations of paragraphs 38-59.

61. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a

declaration that one or more of Barr Laboratories Inc.'s ANDA products do not and will not infringe one or more claims of the '318 patent.

62. Jurisdiction over this counterclaim is proper under 28 U.S.C. §§ 1331, 1338(a), and 2201-02. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

63. There is an actual, substantial, continuing justiciable controversy between Barr Laboratories, Inc. and Plaintiffs/Counterclaim Defendants regarding the non-infringement of the '318 patent.

64. Barr Laboratories, Inc. is entitled to a declaration that one or more of its ANDA products do not and will not infringe one or more claims of the '318 patent.

65. Any additional defenses or counterclaims that discovery may reveal.

RELIEF

WHEREFORE, Defendant/Counterclaim Plaintiff Barr Laboratories, Inc. prays that the Court enter judgment against Plaintiffs/Counterclaim Defendants Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc., and in favor of Defendant/Counterclaim Plaintiff Barr Laboratories, Inc. as follows:

1. For a declaration that the claims of U.S. Patent No. 4,663,318 are invalid;

2. For a declaration that Barr Laboratories, Inc.'s ANDA products do not and will not infringe the claims of U.S. Patent No. 4,663,318;

3. For an award of attorneys' fees pursuant to 35 U.S.C. § 285;

4. For an award of costs; and

5. For such other relief as the Court determines to be just and proper.

Dated: June 30, 2005

PHILLIPS, GOLDMAN & SPENCE, P.A.

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